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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

01-1307
(Serial No. 08/242,384)

IN RE C. STEVEN MCDANIEL, FRANK M. RAUSHEL, and JAMES R. WILD

APPELLANT'S BRIEF

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June 18, 2001

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APPELLANT'S BRIEF

Jurisdictional Statement

This Court has jurisdiction over this appeal from the decision under 35 U.S.C. § 134 of the United States Patent & Trademark Office's Board of Patent Appeals and Interferences ("Board") pursuant to 35 U.S.C. § 141.

Statement of the Issues

- Is a sworn declaration of invention by the sole inventor/s stating that he/they are the sole inventor/s the best such declaration, or must a separate declaration be filed where a publication allegedly disclosing the invention or a portion thereof has an author/authors in addition to the named inventor/s? And, if a separate disclaiming declaration is required, can the statement of the prosecuting attorney who is also the principal inventor provide the

necessary disclaimer?

Can the Patent Office, when examining two separate patent applications disclosing and claiming virtually identical inventions find that the same allegedly prior art references block patentability under 35 U.S.C. § 102 of one but not the other?

- Are the pending claims novel over the cited prior art?

Statement of the Case

Claims 53-64 are pending in the case. The rejection of these claims under 35 U.S.C. § 112, first and second paragraphs, 35 U.S.C. § 102(a) and/or 35 U.S.C. § 102(b), and 35 U.S.C. § 103 was appealed under 35 U.S.C. § 134 to the Board. The Board held that (i) the examiner's determination that the claims pending in the application were unpatentable under 35 U.S.C. § 112, first and second paragraphs was reversed, and that (ii) the examiner's determination that claims 53, 54, and 58-64 pending in the application were unpatentable under 35 U.S.C. § 102(a) and/or 35 U.S.C. § 102(b) was affirmed ("Board Decision"). In view of the Board Decision that certain of the claims in the pending application were unpatentable under 35 U.S.C. § 102(a) and/or 35 U.S.C. § 102(b), the Board found it unnecessary to separately consider rejection of the claims under 35 U.S.C. § 103.

The Board did not rule on the novelty or obviousness over any cited art of claims 55, 56 or 57.

Appellant appeals to this Court that portion of the Board Decision (ii) affirming the examiner's determination that claims 53, 54, and 58-64 pending in the application were unpatentable under 35 U.S.C. § 102(a) and/or 35 U.S.C. § 102(b).

Statement of the Facts

U.S. Patent Application Serial No. 08/252,384 was filed by McDaniel et al. on June 1, 1994 ("McDaniel Application"), that is a continuation of U.S. Patent Application Serial No. 07/928,540 filed August 13, 1992, and that is in turn a divisional of 07/344,258 filed April 27, 1989. CSMO 0019-0090.

Filed in conjunction with the McDaniel Application was a Declaration of Invention signed by the three named inventors. CSMO 0092-0093.

Claims 53-64 are presently pending in the McDaniel Application that are the subject of this appeal. In relevant portion, the examiner in the McDaniel Application case rejected:

- claims 53, 54, and 58 through 63 as lacking novelty over McDaniel et al., *J. Bacteriology* 170(5):2306-2311 (1988) (referred to in the

Board Decision and further herein as "McDaniel (BY)") or Harper et al. *Applied and Environmental Microbiology* 54:2586-2589 (1988) under 35 U.S.C. § 102(a);

- claims 53, 58, and 60 as lacking novelty over Wild et al., *Proceedings of the 1986 U.S. Army Chemical Research, Development and Engineering Center Scientific Conference on Chemical Defense Research*, pp. 629-34 (1986) (referred to in the Board Decision and further herein as "Wild") under 35 U.S.C. § 102(b);
- claims 61 through 63 as lacking novelty over Wild or McDaniel *Ph.D. Dissertation*, Texas A&M University (1985) (referred to in the Board Decision and further herein as "McDaniel (AZ)") under 35 U.S.C. § 102(b); and,
- claims 53, 54, and 60 as lacking novelty over McDaniel (AZ) under 35 U.S.C. § 102(b).

Board Decision, pp. 3-4.

Of the pending claims, the Board only affirmed the examiner's determination that claims 53, 54, and 58 through 63 lacked novelty. *Board Decision*, pp. 3-4. The Board did not rule on the novelty of claims 55 through 57,

nor did it affirm the examiner's determination that claims 55 through 57 are obvious over any of the cited art under 35 U.S.C. § 103. *Board Decision*, p. 4.

U.S. Patent 5,484,728 to Serdar et al. issued January 16, 1996 ("Amgen Patent"). CSMO 0960-0976. This issued patent discloses and claims at least in part the technology published in Serdar et al., *Bio/Technology* 7(11):1151-1155 (1989), which reference was raised early in the prosecution history of the presently appealed patent application. CSMO 0170-0175.

After all briefing of the appeal to the Board had been completed and shortly before the hearing before the Board, appellant discovered that the Amgen Patent existed. The existence of this issued patent and the following facts related to that issued patent were raised orally at the hearing before the Board.

During the prosecution of that patent application (U.S. Patent Application Serial Number 333,892; "Amgen Application"), the same art cited against the McDaniel Application was raised in novelty rejections of highly analogous claims to those of the McDaniel Application, albeit by a different examiner. These highly analogous claims were allowed over McDaniel (BY) and Harper among other prior art publications (in particular, Serdar et al., *Bio/Technology* 3:567-571 (1985), a publication of the same type as Wild and McDaniel (AZ) over which the presently pending claims stand rejected).

Summary of the Argument

The Board clearly erred in not considering the statements in the record, including the Declaration of Invention as well as the disclaiming sworn statements of the principal inventor/prosecuting attorney, that obviate McDaniel (BY) and Harper as prior art. The Board has also clearly erred in not considering the substantial evidence of teaching away over Wild as well as McDaniel (AZ). The prior art rejections made by the examiner and affirmed by the Board are erroneous. The Board did not affirm the examiner's rejections of at least claims 55, 56, and 57, thereby placing them in condition for allowance. As a result of the errors made in the prosecution and appeal of the presently pending patent application, the Patent Office is left contradicting itself in allowing analogous claims in the Amgen Patent to others who were admittedly second-in-time in discovering the gene and its uses. Such a holding is arbitrary, capricious, an abuse of discretion and unsupported by substantial evidence.

Argument/Statement of the Standard of Review

STANDARD OF REVIEW:

The standard of review to be used by the Court in this appeal is delineated in

Dickinson v. Zurko, 119 S.Ct. 1816 (U.S. 1999). That case holds that this Court will review a decision of the Board under standards set forth in the Administrative Procedure Act which permit the Court to set aside agency findings of fact found to be arbitrary, capricious, and abuse of discretion, or unsupported by substantial evidence. 5 U.S.C. § 706.

ARGUMENT:

All 35 U.S.C. § 112 Rejections Have Been Reversed and Are Not Appealed

The Board reversed the examiner's determination that the pending claims were unpatentable under 35 U.S.C. § 112, first and second paragraphs. Appellants do not appeal that portion of the Board's decision.

Claims 55, 56, and 57 Appear to be Allowable and, If So, Are Not Appealed

At a minimum, in view of the Board's holding that all bases for rejection of claims 55 through 57 have been reversed or not reached in any regard, claims 55, 56 and 57 stand allowed. Appellant does not appeal the allowance of claims 55, 56 or 57.

No Declaration Is Needed to Remove Publications In Which The Co-inventors Are Co-authors Other than The Declaration of Invention

The McDaniel (BY) publication was published May 1988. The Harper publication was published in October 1988. Both of these pre-filing publications were published less than one year before the McDaniel Application was filed in April 1989.

The *Manual of Patent Examination Procedures* § 715.01(c) provides one option for removing such a publication from consideration by the examiner as prior art:

> Where the applicant is one of the co-authors of a publication cited against his application, he is not required to file an affidavit or declaration under 37 C.F.R. § 1.131. The publication may be removed as a reference by filing a disclaiming affidavit or declaration of the other authors. *Ex parte Hirschler*, 110 U.S.P.Q. 384. [emphasis added]

Thus, one way that a co-authored, pre-filing publication of an inventor may be removed is by disclaiming affidavit or declaration of his/her co-authors who are not inventors.

The McDaniel (BY) reference was co-authored by McDaniel, Harper, and Wild. The Harper reference was co-authored by Harper, McDaniel, Miller and Wild. Co-inventor Rauschel was not an author on either of these publications. The additional co-authors of both the McDaniel (BY) and Harper references who

were not inventors were either technicians (Ms. Harper) or students (Dr. Miller) working in conjunction with and at the direction of the inventors in order to reduce the inventions of McDaniel, Wild and Rauschel to practice. As offered by the appellant throughout prosecution of the patent application, failing removal of these references as prior art on the other grounds argued, a disclaiming affidavit/declaration will be submitted from both Ms. Harper and Dr. Miller.

However, a co-author's disclaiming affidavit/declaration is not the only manner in which such a publication may be removed. In *In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (CCPA 1982), the Court held that disclaiming affidavits/declarations were not necessary. That court stated that authorship does not give rise to any presumption regarding inventorship. The only requirement appears to be a "reasonable showing supporting the basis for the appellant's position." 21 U.S.P.Q. at 18. The examiner, under this case law, is not free to speculate about the alternatives in the face of the applicant's own satisfactory explanation. *See, In re Kusko*, 215 U.S.P.Q. 972 (PTO Bd. App. 1981) (reaching the same opinion).

The Declaration of Invention filed in conjunction with the McDaniel Application is in accord with these cases in providing a "sworn satisfactory explanation" of the inventorship of the present application. That Declaration made

by each of the co-inventors, two of whom were also co-authors of the McDaniel (BY) and Harper references, states in relevant portion:

> I believe I am the original, first and sole inventor (if only one name is listed below) or the below named inventors are the original, first and joint inventors (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled RECOMBINANT ORGANOPHOPHORUS ACID ANHYDRASE AND METHODS OF USE, the specification of which is attached hereto.
>
> . . .
>
> I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims.
>
> I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

This Declaration could not be more explicit, and is sworn by both of the co-authors who would file a disclaiming affidavit/declaration were that option the only option. It clearly excludes any other person as being an inventor, including any other co-author of either McDaniel (BY) or Harper (both of which references were disclosed by applicants in an Information Disclosure Statement. CSMO 0112-0135).

The Board appears to take the position that a specific citation to the pre-filing publications is required. *Board Decision* at p. 14. Such an addition would add nothing over the sworn statements already in the case. If one or both of the co-

authors had perjured himself with his statement in his Declaration of Invention by knowingly excluding a person as an inventor who was a co-author of either pre-filing publication, he would perjure himself no less by specifically reciting the pre-filing publication/s.

The actual style of the Declaration of Invention in the *In re Katz* case was merely specific to the facts of that case. Namely, the declarant was the sole inventor of both the subject matter of the pre-filing publication as well as the subject matter of the patent application. What if that were not the case? Using the logic of the Board, such a declarant would presumably be required to specifically recite those portions of the pre-filing publication in which he was not the sole inventor, as well as providing a statement concerning his sole inventorship of the subject matter of the patent application. This is a slippery slope. Far better is the simple and imminently challengeable declaration of inventorship of a style such as that used by the present co-inventors.

Even so, as in *In re* Katz, in the present case there are unique facts related to the declaration of inventorship and co-authorship of the pre-filing publications. Erroneously, these facts were not addressed in the Board's decision, although they were clearly raised in the appellant's brief at CSMO 0448-0449.

The principal inventor who directed the work of both Ms. Harper and Dr.

Miller (McDaniel) is, in fact, the prosecuting attorney in the case and the real party in interest bringing this appeal. He is also the person who signed, fully under his ethical obligations as a member of the patent bar in good-standing, the statements made during prosecution of the application disclaiming any role in inventorship for Ms. Harper or Dr. Miller. CSMO 0178-0180, CSMO 0208.

Indeed, the pre-filing publications were specifically referenced in these statements as was done in the declaration of invention of *In re Katz*. CSMO 0178-0180. Patent attorney McDaniel stated in the record that he was the inventor principally supervising Ms. Harper and Dr. Miller to assist in merely reducing to practice his and the other named inventors' inventive conceptions. CSMO 0179. Attorney McDaniel also stated on the record (appellant's appeal brief) that he was, as were the other inventors (and, for that matter, as were Ms. Harper and Dr. Miller), under a common duty to assign any and all inventions to the original and common assignee (Texas A&M University). CSMO 0449. Thus, the appellant has provided more than one "sworn satisfactory explanation" of the inventorship of the present application.

The Rejection of Claims 53, 58 and 60 over Wild

The Board takes the position that the invention as claimed in claim 53 (and,

presumably, claims 58 and 60) "is not directed to the opd gene or the use thereof."[1] *Board Decision* at CSMO 0015. This is certainly not the position taken by the examiner that was appealed to the Board.

As discussed at length in the applicant's appeal brief (CSMO 0450), the examiner in rejecting claims 53, 58 and 60 over Wild takes the position that Wild discloses cloning and expression of organophosphorus degrading genes from soil bacteria using a cloned DNA fragment that contained the opd gene. The examiner also takes the position that while the DNA sequence is not disclosed in Wild, that only "routine sequencing would have been needed to determine the sequence." In his appeal brief, therefore, appellant addressed the basis of the examiner's rejection, which clearly assumes that the claimed invention is, in fact, directed to the opd gene or the use thereof.

The USPTO allowed claims to the opd gene and its expressed protein to Amgen over McDaniel (BY) and Harper, references which clearly delineate the invention, as opposed to the Wild reference which does not. The Amgen Patent was granted over not only McDaniel (BY) and Harper, but also over Serdar et al., "Enzymatic Hydrolysis of Organophosphates:Cloning and Expression of a

[1] The Board's arguments regarding rejection of claims 53, 58 and 60 over Wild under 35 U.S.C. § 102(b) are obtuse for a number of other reasons. While the arguments are ostensibly directed at the Wild reference alone, the Board raises in its discussi n the McDaniel (BY) and Harper references to support its position that the claimed recombinant bacterial organophosporus acid anhydrase was not novel. As McDaniel (BY) and Harper are not prior

Parathion Hydrolase Gene from *Pseudomonas diminuta*, *Bio/Technology* 3:567-571 (1985). *Amgen Patent* at CSMO 0960.

Even so, if one takes the Board's position (which is contrary to that of the examiner's vigorous, if wrong-minded, arguments directed at the allegedly incorrect DNA sequence of the invention) and views the claimed bacterial recombinant organophosphorus acid anyhdrase in the abstract in comparison to the recombinant enzyme of Wild, Wild utterly fails to teach the claimed invention. Erroneously, the Board did not discuss and apparently utterly failed to take into consideration the teaching away arguments raised by the appellant in his brief. CSMO 0450-0451.

In fact, if one were to follow the teachings of Wild, one would <u>not</u> obtain a functional enzyme. The Board erred in not acknowledging the plain fact that the Wild reference teaches that it is preferred to obtain the bacterial recombinant enzyme by removing approximately 250 base pairs of DNA form the 5' flanking sequence of the originally cloned fragment. To the contrary, as disclosed by the present invention, removal of such a region of DNA from the cloned fragment results in no enzyme at all, or at a minimum, a non-functional enzyme. CSMO 0451.

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art, it is improper to combine them in this fashion in a 35 U.S.C. § 102 argument. Moreover, neither McDaniel (BY)

McDaniel (AZ) Is a Ph.D. Dissertation Lacking Any Disclosure of the Requisite DNA Sequence Information

As with the Wild reference discussed above, the McDaniel (AZ) reference teaches away from the present claims in important regards. McDaniel (AZ) is a Ph.D. dissertation of one of the co-inventors. It was very preliminary in content. This fact is graphically illustrated by the fact that although there were numerous attempts to sequence the opd gene by the Ph.D. candidate (McDaniel), those attempts failed. CSMO 0183. Had they succeeded, sequence information would have undoubtedly been provided, as that would have strengthened the Ph.D. candidate's defense in large measure. In fact, the examiner expressly noted the lack of such DNA sequence information throughout the dissertation. CSMO 0183-0184.

The Pending Claims Do, In Fact, "Require the Recombinant DNA Sequence of the Invention," and, in At Least Certain Instances Specifically Recite The Entire Sequence

The Board appears to take the position that the pending claims do not require the recombinant DNA sequence of the invention. *Board Decision* at CSMO 0015, lines 8-10; *Board Decision* at CSMO 0016, lines 4-6. This erroneous argument is targeted at distinctions that appellant makes over references that allegedly teach a

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nor Harper are cited under the examiner's arguments on this basis for rejection.

recombinant enzyme, yet do not teach the DNA sequence.

Nothing could be further from the truth. The claims depend on their enablement upon the specification, and the specification teaches that it is critical to understand the DNA sequence in order to make possible the cloning of the gene. Claims 61-63 even specifically recite as a limitation in the body of the claim such DNA sequence:

61. The method of claim 53 wherein said recombinant bacterial organophosphorus acid anhydrase is produced by a transformed organism comprising an expression vector for producing said anhydrase and wherein said vector has a cloned bacterial organophosphorus acid anhydrase gene fragment with the DNA coding sequence:

    [the claimed full-length fragment DNA sequence is thereafter specifically recited in the claim in its entirety].

62. The method of claim 53 wherein said recombinant bacterial organophosphorus acid anhydrase is produced by a transformed eukaryotic cell line comprising an expression vector for producing said anhydrase and wherein said vector has a cloned bacterial organophosphorus acid anhydrase gene fragment with the DNA coding sequence:

    [the claimed full-length fragment DNA sequence is thereafter specifically recited in the claim in its entirety].

63. The method of claim 53 wherein said recombinant bacterial organophosphorus acid anhydrase is produced by a transformed eukaryotic organism comprising an expression vector for producing said anhydrase and wherein said vector has a cloned bacterial organophosphorus acid anhydrase gene fragment with the DNA coding sequence:

[the claimed full-length fragment DNA sequence is thereafter specifically recited in the claim in its entirety].

CSMO0476-0480.

The Patent Granted to Amgen on The Same Invention, Over the Same and Analogous Prior Art Strongly Suggests Error in Rejection of the Present Claims

It is a well-known proposition of patent law that the prosecution of one patent application does not dictate nor affect the prosecution of another patent application, even if the applications are highly analogous. But, in the present case, to apply that proposition results in a manifestly unjust ruling. Moreover, it awards patent claims identical to those appealed in this Court to researchers who were admittedly second-in-time to discover the subject matter of the present invention. And, it denies the same patent claims to those that were first-to-invent.

The pending claims are allowable over the cited prior art. At least they would be allowable had they been examined under the same parameters with which the Amgen Patent was examined.

The Amgen Patent was granted over McDaniel (BY) and Harper, the two principal references over which the presently pending claims have been held unpatentable. CSMO 0960. The Amgen Patent was also held to be patentable over Serdar et al., *Bio/Technology* 3:567-571 (1985). The later reference does not

disclose DNA sequence but does suggest cloning strategies for the parathion hydrolase (organophosporus acid anhydrase) gene. *Amgen Patent* at CSMO 0970, column 3, line 42-column 4, line 67. Therefore, the later reference is a reference highly analogous to that of Wild and McDaniel over which the presently pending claims are rejected.

The principal cited prior art in the prosecution of the presently appealed patent application is virtually identical to that cited against the Amgen Patent. The Amgen Patent covers the same subject matter as that of the presently appealed patent application. That issued patent has claims that are similar in scope and breadth to the pending claims on appeal. To hold the Amgen Patent allowable and the McDaniel et al. patent application otherwise over the same prior art is unjust.

Conclusion and Statement of Relief Sought

CONCLUSION:

The Board has clearly erred in not considering the statements in the record, including the Declaration of Invention as well as the disclaiming sworn statements of the principal inventor/prosecuting attorney, that obviate McDaniel (BY) and Harper as prior art. The Board has also clearly erred in not considering the substantial evidence of teaching away over Wild as well as McDaniel (AZ). The

Board did not affirm the examiner's rejections of at least claims 55, 56, and 57, thereby placing them in condition for allowance.

As a result of the errors made in the prosecution and appeal of the presently pending patent application, the Patent Office contradicts itself in holding that the cited prior art blocks the grant of the pending claims. It has allowed analogous claims in the Amgen Patent to others who were admittedly second-in-time in discovering the gene and its uses. Moreover, the Patent Office allowed these analogous claims over the same prior art and highly analogous art cited against the pending claims. This contradiction cannot be allowed to stand as it represents a finding of fact that is arbitrary, capricious, an abuse of discretion and unsupported by substantial evidence.

STATEMENT OF RELIEF SOUGHT:

Appellant requests that the Board's decision as it relates to affirming the examiner's prior art rejections for claims 53, 54, and 58-64 be overturned and that the prosecution of the pending claims be permitted to continue. At a minimum, the Court is requested to instruct the Board to move to allowance claim 55, 56, and 57.

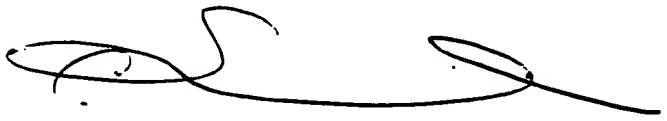
If it is deemed that a disclaiming declaration under 35 U.S.C. § 131 is necessary, appellant requests that the Court order that appellant be allowed to enter

such a declaration into the case.

It is also requested that any delay attributable to Patent Office delay such as that necessitated by the improper rejection of the appellant's claims be ordered by this Court to be added to the maximal extent possible to the terminal end of any patent allowed.

In continuing the prosecution of the pending claims, it would be most judicially and administratively efficient for the Court to order that an interference be initiated between the pending application (or any patent to issue therefrom) and U.S. Patent 5,484,728.

Respectfully submitted:



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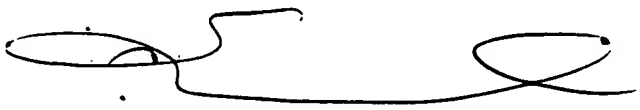
Certificate f Compliance

I hereby certify that I, C. Steven McDaniel, that this Appellant's Brief is in compliance with Rule 32(a)(7) having under the allotted 14,000 words and 1,300 lines of text. This Appellant's Brief contains 4,091 words and has 455 lines of text.



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CERTIFICATE OF SERVICE

I hereby certify that on June 18, 2001, I caused one copy of the foregoing APPELLANT'S BRIEF to be mailed by United States mail (first-class, postage prepaid), addressed as follows:

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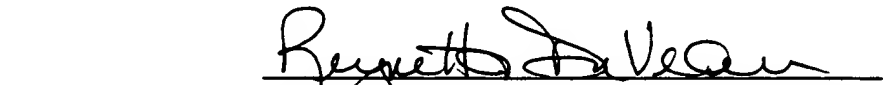

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